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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/580,447
Filing Date: May 23, 2006
Appellant(s): GREENHALGH ET AL.

Sheila A. Loggins
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed May 4, 2010 appealing from the Office action mailed December 11, 2009.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claim 13 is cancelled.

Clams 1-12 and 14-18 are pending.

Claims 1-12 and 14-18 are rejected and on appeal.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| US 5,334,519 | Yamada et al. | 08-1994 |
| US 5,352,828 | Seki et al. | 10-1994 |

Leonova, T.E., et al. "Nitrile Hydratase of *Rhodococcus*." *Applied Biochemistry and Biotechnology*, vol. 88 (2000), pp. 231-241.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-12 and 14-18 stand rejected under 35 U.S.C. 103(a) as obvious over Yamada et al. (US Pat. 5,334,519) in view of Seki et al. (US Pat. 5,352,828) and

Leonova et al. ("Nitrile Hydratase of *Rhodococcus*." *Applied Biochemistry and Biotechnology*, vol. 88 (2000), pp. 231-241). The claims recite a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtained from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation broth, forming the polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture comprising the ethylenically unsaturated monomer and cellular material and/or components of a fermentation broth in the presence of a redox and/or thermal initiator and the formed polymer exhibits an intrinsic viscosity of at least 3 dl/g measured using a suspended level viscometer in 1 M sodium chloride at 25 degrees C. The claims further recite that the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and/or components of a fermentation broth and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism. The claims further recite that the biocatalyst comprises a microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism. The claims further recite that the cellular material comprises whole cells. The claims further recite that the cellular material comprises fractured cellular material, specifically wherein the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell

nucleus material, cytoplasm and proteins. The claims further recite that the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators, enzyme inducers and complex fermentation medium components. The claims further recite that the ethylenically unsaturated monomer is methacrylamide monomer. The claims further recite that the substrate is methacrylonitrile. The claims further recite that the biocatalyst comprises a nitrile hydratase enzyme. The claims further recite that the polymer is a homopolymer or copolymer of methacrylamide. The claims further recite that the ethylenically unsaturated monomer is selected from the group consisting of itaconic acid (or salts thereof), maleic acid (or salts thereof) and methacrylic acid or salts and derivatives thereof. The claims further recite that the substrate is introduced into a vessel and contacted with a biocatalyst and wherein the substrate is converted into the ethylenically unsaturated monomer, optionally introduction other monomers into the vessel to form a monomer mixture, subjecting the ethylenically unsaturated monomer or monomer mixture to polymerization conditions, optionally by introducing initiators into the vessel, and thereby forming the polymer inside the vessel. The claims further recite that the biocatalyst is produced inside the vessel. The claims further recite that the biocatalyst comprises microorganisms of the *Rhodoccocus* genus. The claims further recite that the microorganism is *Rhodococcus rhodochrous* NCIMB 41164. The claims recite a composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or components of a fermentation broth, wherein the composition is obtained by a process according to claim 1.

Yamada teaches a process for preparing an acrylamide (such as methacrylamide, an ethylenically unsaturated monomer) in which the monomer is obtained from a biocatalysed reaction or fermentation process wherein the substrate (a nitrile such as methacrylonitrile) is contacted by a biocatalyst that comprises a microorganism or cellular material and thereby converted into the monomer (abstract, col. 12, lines 12-40). In the process of Yamada, after the substrate is converted into a monomer, it contains cellular material and/or components of the fermentation medium, such as complex fermentation components (col. 12, lines 12-40). In the process of Yamada, the cellular material may comprise whole cells or fractured cellular material, such as cell wall material, and the process would inherently occur inside of the cell and form part of a metabolic process (col. 8, lines 1-39). Yamada teaches that the biocatalyst comprises *Rhodococcus rhodochrous*, which comprises nitrile hydratase (abstract). The process of Yamada occurs inside of a bioreactor or vessel (col. 8, lines 21-25, col. 12, lines 12-40). Yamada teaches that iron may be added to the medium (col. 9, lines 5-24).

Yamada does not teach the formation of a polymer (homopolymer or copolymer of methacrylamide) in the vessel comprising the ethylenically unsaturated monomer wherein the unsaturated monomer comprises cellular material and/or components of the fermentation broth. Yamada does not specifically teach the claimed viscosity or the use of *Rhodococcus rhodochrous* NCIMB 41164 as the biocatalyst.

Seki teaches that polymerization of a solution of acrylamide (an ethylenically unsaturated monomer) will occur under many conditions, such as in the presence of iron (col. 2, lines 13-19, col. 1, lines 45-49).

Leonova teaches the production of nitrile hydratase, the enzyme that converts a nitrile to an amide and which is recited in the instant claims, by the organism *Rhodococcus rhodochrous* M8.

At the time of the invention, a process of preparing a monomer comprising nearly all of the claimed elements was known, as taught by Yamada. It was further known that solutions of monomers are likely to polymerize if they are not stabilized, as taught by Seki. Since the method of Yamada does not explicitly teach stabilizing the fermentation broth against polymerization, it is either inherent to the teachings of Yamada, or it would occur during routine optimization and experimentation, that polymerization of the monomer in solution, such as in the fermentation broth, would occur. For instance, Yamada teaches that it may be desirable to add iron to the medium in order to alter enzyme activity; since Seki teaches that iron may initiate polymerization, one of ordinary skill in the art would have been motivated to modify the teachings of Yamada in the course of routine experimentation such that the process would result in the polymerization discussed by Seki. Since iron is a metal and may initiate polymerization, it may be considered a redox initiator. One of ordinary skill in the art would have a reasonable expectation of success in polymerizing the fermentation broth taught by Yamada because polymerization of acrylamide solutions is known to occur in such solutions spontaneously, as taught by Seki. The spontaneously produced polymer of Yamada would either be a homopolymer or copolymer of methacrylamide. Seki teaches that the claimed polymer may be popcorn-like (col. 5, lines 14-21); it therefore appears that the polymer, once separated from the mixture, would exhibit a solidity that would place it within the claimed viscosity range. Furthermore, although none of the

references specifically disclose the use of the claimed strain in the method for the production of polymers, the microbial species *Rhodococcus rhodochrous* was known in the time of the art to perform the biocatalytic reaction recited in the claims, as taught by Yamada and Leonova. The selection of a strain of a known organism for use in a known method would have been a matter of routine experimentation to one of ordinary skill in the art. One of ordinary skill in the art would have had a reasonable expectation of success in using a strain of *Rhodococcus rhodochrous* in the claimed method because members of the species were known at the time of the invention to be useful for the production of the monomers recited in the claims. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

**(10) Response to Argument**

Appellants argue that the teachings of the applied references do not anticipate or render obvious the claimed invention. Specifically, Appellant argues that, since Yamada does not teach that polymerization takes place in the presence of contain cellular material and/or components of the fermentation broth, one of ordinary skill in the art would not have considered it obvious for polymerization to have taken place under these conditions.

In response to Appellant's argument, it is noted that this feature of the claims is rendered obvious by the teachings of Seki. The reference teaches that solutions of

monomers are likely to polymerize if they are not stabilized. Since the method of Yamada does not explicitly teach stabilizing the fermentation broth to prevent polymerization, the initiation of polymerization in the fermentation broth of Yamada would either be inherent to the teachings of the reference, or would occur during routine optimization and experimentation by one of ordinary skill in the art practicing the method of Yamada. Furthermore, Appellant has not specified the precise components of a fermentation broth that must be present in the monomer or monomer mixture that is polymerized. Since the monomer is synthesized from a substrate that is a component of the fermentation broth, such as methacrylonitrile, even a purified solution of the resultant methacrylamide monomer would contain elements from the methacrylonitrile chemical compound; thus, the polymerization of a partially or fully purified mixture prepared from the substrate would meet the claim limitations. Therefore, although Appellant argues that polymerization of a monomer or monomer mixture that contains cellular material and/or components of a fermentation broth is not rendered obvious by the cited prior art, this argument is not found to be persuasive.

Appellant further argues that there is no indication that the polymer produced in the Seki reference would exhibit the intrinsic viscosity recited in the claims. Specifically, Appellant argues that the polymer of Seki is popcorn-like and that such polymers do not swell in solvent and therefore would not exhibit a viscosity within the claimed intrinsic viscosity range. However, Appellant has not provided any evidence to support this assertion. Furthermore, although Seki teaches the formation of popcorn-like polymer, the reference further teaches that polymerization is a sensitive process and that unstabilized solutions of monomers may spontaneously polymerize. The popcorn-like

monomer of Seki is provided as an example of this phenomenon. Since the viscosity range provided in the claims is broad, and since Seki teaches the likelihood of a spontaneous polymerization of a solution of monomers, the production of a polymer exhibiting intrinsic viscosity within the claimed range by the routine alteration of the method of Yamada would have been obvious. Therefore, Appellant's argument is not found to be persuasive.

Appellant also argues that the claimed invention presents an unexpected result, specifically, that one of ordinary skill in the art would not have expected the polymerization of an unpurified solution of monomer to be successful. It is noted, however, that the claims do not recite the polymerization of an unpurified solution; rather, the claims recite that the monomer or monomer mixture comprises cellular material and/or components of a fermentation broth. It is submitted that, even if the prior art teaches that it is desirable to remove some components from the monomer mixture prior to polymerization, one of ordinary skill in the art would not expect a purification process to remove each and every one of these components, and that polymerization of a solution that contains some impurities or other cellular or broth components is likely, as taught by Seki. Thus, Appellant's argument is not commensurate in scope with the instant claims.

Therefore, Appellant's arguments as a whole have not been found to be persuasive.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Sheridan R. MacAuley/
Sheridan R. MacAuley, Examiner, Art Unit 1651

Conferees:

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